THE CAUSES OF FAILURE TO TRANSPLANT CADAVERIC HUMAN ORGANS

Final Report

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EXECUTIVE SUMMARY

Study Purpose and Methods

In August 1986, Brandeis University was awarded cooperative agreement No. 17-C-98728 by the Health Care Financing Administration (HCFA) and, in September 1986, a supplemental agreement by the Division of Transplantation of the Public Health Service (PHS) to conduct a study of "the causes of failure to transplant cadaveric human organs." The National Kidney Disposition Study was undertaken to document the process of donor retrieval, the nephrectomy, and organ placement for a large sample of cadaveric donors. The primary goal of the research was to examine incidences of failure to transplant kidneys and to identify the causes of organ discard decisions.

OPOs were asked to complete a Kidney Disposition Form for each donor and return forms monthly. Donor condition was to be noted prior to the nephrectomy, but in some cases later procurement events or outcome may have influenced the subjective assessment of donor rating scale. This information therefore should be interpreted with caution.

Organ disposition data were collected for 3646 individual kidney cases. In 143 cases, one agency had imported a kidney from another agency in the sample, producing duplicate information. Excluding these duplicate cases, the analyzable dataset includes a total of 3503 kidneys. Of these, 3,261 were reported transplanted, 181 were discarded, and 61 had unknown outcomes. Neither the agencies nor UNOS, responsible for 51 missing outcomes, were able to provide this information.

Major Findings

Descriptive Characteristics

- Donor attributes

  Most of the kidneys in the study reported here came from donors who were likely to be white and male. half of the donors were between the ages of 11 and 30. A surprising 6 percent of donations are from people over 55, and even some donations from people over 65 (n=19). Kidneys from pediatric donors, defined here as those ten years old and less, represent less than 12 percent of kidneys. Most kidneys (64 percent) came from donors who had died of trauma-related diagnoses due to motor vehicle or other accidents. OPOs assessed the majority as satisfactory or optimal donors. Eleven percent were rated as marginal by procurement coordinators.

- The nephrectomy process

  A transplant surgeon performed the nephrectomy in 82 percent of the cases; 11 percent of the time kidneys were excised by local surgeons, and residents or fellows were responsible for less than 6 percent of the kidney procurements. Typically, kidneys were removed en bloc and insitu flush was the preferred beginning of organ preservation. The most common preservation medium was slush, but perfusion, which had been declining in usage, was employed 11 percent of the time by

itself and an additional 6 percent in combination with slush. The rise in the use of perfusion may indicate attempts to preserve increasing numbers of kidneys from very young donors, kidneys that will travel long distances, or kidneys that appear marginal and are tested for viability on the perfusion machine.

- o Organizational characteristics

  Organ placement and sharing practices have long been a focus of analysis of the effectiveness of the U.S. organ procurement system. Among agencies reporting for the 1988 National Kidney Disposition Study, nearly three quarters of all kidneys procured were kept by the locally procuring OPO. The remainder were shared: 14 percent were exported to other agencies, and 12.5 percent were imported from them directly or via UNOS. Less than one percent were re-exported.

Causes of kidney discard

Ninety-three percent of kidneys were transplanted, 2 percent had unknown outcomes, and 5 percent were discarded. Causes of kidney discard were related to donor, nephrectomy, and organizational characteristics.

- o Donor characteristics

  Kidneys were more likely to be discarded if they were retrieved from marginal donors (20 percent discarded), from donors whose cause of death was listed as illness (10 percent), or from pediatric donors (8 percent). Kidneys were less likely to be discarded if the door were pre-typed before the nephrectomy process began (3 percent).

- o Nephrectomy characteristics

  Kidneys were more likely to be discarded if a local surgeon, rather than a transplant surgeon, retrieved them (8 percent), or if insitu flush was not used as a method of preservation (12 percent). They were less likely to be discarded if the donor had also donated a heart or a liver (3 percent) and they had not been removed enbloc (2 percent).

- o Organizational characteristics

  In general organs that were exported had lower discard rates (4 percent) but this interpretation s confounded by the fact that over 8 percent of exported kidneys had unknown outcomes.

- o Reasons for discard cited by OPOs

  More than 76 percent of reasons for kidney discards reported by OPOs are due to 5 major causes. Donor/organ pathology are cited for 29 percent of discard outcomes; anatomic abnormalities for 17 percent, surgical complications account for 11 percent as do positive cultures, and organ injury prior to nephrectomy was given 9 percent of the time as the reason for discard.

Kidney discard decisions within special populations

- Kidneys from minority donors

  There are no statistically significant differences in donor, procedural or organizational characteristics between discarded kidneys from minority and non-minority donors. Although there is a higher percentage of discarded kidneys among donors rated as marginal, this differences does not reach statistical significance. Fewer minority kidneys were imported, but this is also not statistically significant.

The ranking of discard reasons differs for kidneys from minority and non-minority doors. Positive cultures (21 percent), surgical complications (15 percent), donor/organ pathology (15 percent), and prior organ injury (13 percent) account for nearly two-thirds of reasons given for discards of minority kidneys. Positive cultures and prior organ injury are more frequent causes of discard for minority than non-minority kidneys; donor/organ pathology and anatomical abnormality are much less frequent. However, these differences do not reach levels of statistical significance.

- Kidneys from pediatric donors

  Discarded kidneys from pediatric donors are much less likely to have a marginal rating than discarded adult kidneys (12 vs 49 percent), much more likely to have come from those who were also liver donors (59 vs 17 percent), and more likely to have been preserved with insitu flush (96 percent), and more likely to have been shared (imported 19 vs 7 percent; exported 41 vs 6 percent).

Most pediatric kidneys were discarded because they were too small (38 percent), there were surgical complications (22 percent) or an anatomic abnormality was discovered that could not be corrected (16 percent).

- Kidneys from marginal donors

  Organ discards from marginal donors are less likely to come from pediatric donors (4 percent marginal, 25 percent non-marginal), they are more likely to have been perfused (30 vs 6 percent), less likely to be flushed insitu (63 vs 89 percent) or to be a heart donor (19 vs 37 percent) or a liver donor (3 vs 36 percent). Among kidney discards from marginal donors, there were no exports.

The main reasons given for discard of marginal kidneys were donor/organ pathology (44 percent), positive cultures (13 percent), preservation problems (13 percent).

The analysis of organ discard decisions of kidneys from special populations such as minority, pediatric and marginal donors reveals some interesting findings. First, discards are not more likely to come from minority donors than white donors. Second, kidneys from pediatric donors are most likely to be discarded due to the small size of the donors and the surgical

complications ensuring from trying to procure them. Third, kidney wastage from donors rated as marginal by the procuring OPO is surprisingly limited. Although it far exceeds wastage from other groups, about 80 percent of kidneys retrieved from marginal donors result in a transplant.

Multivariate Findings

Regression analyses were performed on procurement outcome for four subsamples of the kidney disposition data: locally procured and kept kidneys (n=2530), pediatric kidneys (n=387), marginal kidneys (n=333), and minority kidneys (n=649).

The regression analyses demonstrate that donor characteristics, the nephrectomy procedure, and the OPO influence procurement outcomes. Donor characteristics influence discard decisions among all subsamples. Young donor age and low donor weight, illness as cause of death, and having an AB blood type contribute to discard decisions for all samples analyzed. The nephrectomy procedure characteristics seem to have the strongest impact on the discard of local kidneys: enbloc procurement and the use of perfusion are both predictors of discard decisions for all groups. But it is the organ sharing attributes that are the most prevalent predictors of discards among special populations: kidneys from pediatric, marginal and minority donors. It is for these groups that a national system may have the most effect on reducing organ wastage.

Site Visit Findings

Five OPOs were visited to gain a more comprehensive understanding of the quantitative data. Agencies were selected for their model of organ procurement and their low discard rates.

- Sites visited were well-organized, with extensively trained procurement staff, frequent and well-planned in-service programs for area hospitals, and clear relationships with local transplant programs.
- The OPOs visited reported good relations with other procurement agencies and with UNOS.
- Sites visited differed from OPOs not selected for visit in the following ways:
  - They were less likely to discard organs for reasons of organ pathology or positive cultures, indicating that donors with these problems may be screened out before a nephrectomy.
  - Half of the organs discarded due to surgical complications come from the visited OPOs. Half of these discards are due to damage caused by a surgeon removing another organ, usually the liver.

- The visited sites had virtually no wastage occuring after a successful nephrectomy. In most cases, suitable recipients were found for viable kidneys early in the procurement process.

- Sites visited were more likely to pre-type their donors, have transplant surgeons remove the kidneys, and make transplant or discard decisions faster than other sites.

Sites visited continued to have some kidney wastage. In general, they aggressively pursue donors and are willing to risk that some procured kidneys will not be transplanted.

Recommendations

- Some kidney wastage is an inevitable result of an aggressive organ procurement policy.

- Some types of discard can be reduced.

  - Surgical errors due to inexperience could be reduced with improved organ removal training programs.

  - Procurement and transplant experts should develop a commonly accepted etiquette for multi-organ removal. This could reduce the number of kidneys damaged in the procurement of hearts and livers.

  - Kidney discards due to small donor size could be reduced if pediatric procurements were pursued with known recipients already identifed.

  - Scheduling the nephrectomy after tissue cultures prove negative would reduce some discards due to the late discovery of infections in donors.

- Guidelines should be developed to address these problems, but strict regulations should be avoided at this time because they might lead to a decrease in donors or donor referrals.

The increasing demand for transplantable cadaveric organs makes it imperative that all organs that can be procured are, and that all organs that are procured are used. The findings from this study may be useful in helping policymakers improve organ sharing to reduce kidney discard.

Chapter 1

INTRODUCTION

Purpose of the study

In 1986 the Health Care Financing Administration (HCFA), in conjunction with the Office of Transplantation, funded a three-year study to examine the problem of organ wastage in the U.S. The focus of the study was on the causes of failure to utilize cadaveric human kidneys. To identify these causes, a four stage research plan was carried out:

- a facility survey of all 99 organ procurement organizations (OPOs) operating in 1987 was conducted;
- key informant interviews were conducted with organ procurement organization (OPO) staff in 6 representative agencies to construct a working model of kidney disposition in the U.S.;
- 25 OPOs, which obtained more than half of the kidneys procured in 1988, were surveyed monthly for one year to collect data about every kidney that passed through the agency to test the model. Data were collected on over 3500 kidney procurements; kidneys were discarded in 181 instances;
- validation interviews were conducted with 5 OPOs selected for their success in maintaining high levels of procurement and controlling kidney wastage.

The study results reported here provide a comprehensive analysis of kidney disposition and wastage in the U.S. at the end of the eighties. This final report is divided into 8 chapters. They include

- an introduction establishing the purpose of the study and providing an historical overview of kidney procurement and wastage;
- a discussion of the data and methods used to conduct the study;
- a description of U.S. kidney disposition based on study results;
- an examination of kidney discard by donor characteristics, procurement events, and organ sharing practices;
- an assessment of organ discard from donors of pediatric, marginal, and minority kidneys;
- an analysis of the impact of the organizational process on kidney disposition;
- the identification of variables predicting kidney discard derived from a multivariate analysis; and

- studies of organ discard among 5 OPOs with predominantly favorable kidney procurement outcomes.

History of the problem

The gap between the supply and demand for cadaveric organs has never been greater. From 1986 through 1988, cadaveric organ supply remained flat at about 7,000 cadaveric organs transplanted each year.[1] In spite of kidneys being provided to people at this rate, the numbers of those currently on waiting lists continues to grow, increasing nearly 15 percent from December 1988 to December 1989.[2] The increases are believed to be due to the growing recognition that transplantation offers the best quality of life to recipients.[3] New listings are the result of more physician referrals and increased referrals of patients who are older and sicker.

The shortage of organs has been addressed through innovations in medical technology, public and professional education, changes in federal regulations, and improvements in the organization of the procurement system. Medical innovation has been the most dramatic cause of increasing transplantation. Ongoing medical research for the suppression of the human rejection response has made it possible to more carefully match donors and recipients and increase the chances of patient and organ graft survival. The discovery and development of new anti-rejection drugs such as cyclosporine, monoclonal antibodies, and most recently FK-506, has also made it possible to keep more transplanted organs functioning.

Of the various remedies proposed to decrease or at least minimize the gap between supply and demand, public education has long received the most popular support. Surveys of organ procurement professionals and the general public all recommend stimulating public awareness of the need for donation through the mass media and other vehicles of public education.[4] Great effort has been expended on public education, at first by the National Kidney Foundation and more recently by the American Council of Transplantation and the efforts of local organ procurement agencies throughout the country. It has been clearly established through national survey research that the vast majority of the American public is aware of organ transplantation as a therapeutic medical technology, and most members of the general public voice support for altruistic organ donation as the method to provide the organs needed for transplants. While public education may have had an important initial effect on donation which doubled from 1982 to 1988,[1] flat donation over the past three years indicate that more must be done to increase rates of organ supply.

Professional education has been one strategy utilized to address reluctance among medical providers who must refer potential donors to OPOs.[5] Many physicians are not comfortable interacting with families about death.[6] Neurosurgeons may hesitate to become involved in an organ procurement because of the emotional and time costs. In addition, neurosurgeons express concerns about legal liability, possibly reflected in an acknowledged dislike of determining death by brain-death criteria.

The referral of potential donors to OPOs depends on physician support and the support of other hospital professionals. The attitudes of hospital administrators and nursing staff towards involvement in organ donation has been shown to correlate positively with these professionals' perception of the strength of physician support for organ procurement.[5] This finding underscores the importance for professional education to address resistance to organ procurement through in-service programs for nursing staff and colleague-sponsored medical education for neurosurgeons and other physicians.

Federal regulation of and payment for organ procurement has also been used to increase organ supply. The federal government is committed to increasing organ supply and has funded the treatment of end-stage kidney disease since 1972. The Health Care Financing Administration (HCFA), the regulatory agency that administers Medicare and pays for the costs of treatment of end-stage renal disease (ESRD), has regulated organ procurement and collected data on the problem since the mid-seventies. Congressional interest in the problem resulted in the passage of the National Organ Transplant Act in the mid-eighties. A national Task Force on Organ Transplantation produced recommendations to improve the efficiency of the system and the effectiveness of individual organ procurement agencies. Recommendations which have been implemented have included the establishment of a national computer registry and equitable allocation rules. However, despite more effective public and professional education, federal regulation, and continuing medical innovation, the gap between organ demand and supply continues to grow with more than 17,000 people still waiting for kidneys.[7]

With organs in such short supply, it is imperative to maximize the effectiveness of the existing supply. Indeed, the most telling indicators of a system's effectiveness are its efficiency and its wastage rate.[8] Between 1980 - 1984, the kidney wastage rate, kidneys that were procured but not transplanted, was variously estimated to be between 10[9] and 20 percent.[10] In contrast, Eurotransplant, the largest European organ procurement system claimed, as that time, to have a wastage rate no greater than 7 percent.[11] Within the U.S. itself, kidney wastage varied dramatically from 2 percent in some agencies to over 46 percent in others.[12]

Some organ wastage was deemed to be inevitable because of anatomical abnormalities, organ pathology or organ injuries which may not become evident until surgery begins. However, a review of the literature, summarized in Table 1:1, on the incidence of renal abnormalities shows the relative rarity of most of these conditions. While anomalies of renal vasculature are most common (and most easily repaired by transplant surgeons), other conditions are much less likely to present in an organ procurement. The most frequent of these include renal malrotation, horseshoe kidneys, adult polycystic kidney disease, and unilateral hypoplasia..

anomalies should go here

Anatomic abnormalities would have to exceed more than 100 times their present rates to cause 10 percent of organ wastage. Undetected organ pathology or organ injury are more likely causes of organ discards during a procurement. But the incidence of these events should be similar among the U.S. and European populations. The disparity in wastage rates between the U.S. and European systems and among U.S. agencies implicate other causes of organ discard. Discussions with organ procurement experts indicate that these are likely to include differences in the definition of a discarded kidney, surgical error in procuring cadaveric organs, donor quality issues, and organizational problems in placing acquired organs.

The increasing demand for transplantable cadaveric organs makes it imperative that all organs that can be procured are, and that all organs that are procured are used. The National Kidney Disposition Study was undertaken to document the incidence of organ wastage in a large sample of procured kidneys. The following report documents the 'careers' of kidneys in 1988 and analyzes the problem of organ wastage in the U.S. organ procurement system.

Chapter 2

DATA AND METHODS

Data Sources and Sampling Design

Identification of the OPO universe

Data on kidney disposition were collected from six sources. First, a review of public documents was used to identify the universe of Medicare approved organ procurement organizations (OPOs) with their current addresses, telephone numbers, and reported cost data. One hundred and ten OPOs were thus identified, 56 of which were believed to be independent organ procurement agencies (IOPAs). This became the sampling frame for the remainder of the study. (This study commenced prior to the most recent round of OPO certification,)

Mail survey of OPOs

Second, a mail survey of the OPOs was conducted in early 1987. Of the 110 originally contacted, 11 indicated they were not actively in operation as organ procurement agencies, reducing the effective universe to 99 agencies. Responses were received from 86 OPOs, giving an overall response rate of 86.9 percent.

The survey instrument was developed, pretested, and revised. The extensive 15 page survey covered a variety of topics including the agency's procurement activities, personnel practices and service area. State maps covering the area in which the agency was located were enclosed and respondents were asked to mark those areas on the map which their agency served.

Exploratory site visits

Third, site visits were conducted with OPOs. A sampling strategy to visit representative agencies was developed. Eight OPOs were selected by region, size, organizational type, and wastage rates for site visits. Six agreed to cooperate in the study and were visited in the spring of 1987. An interview agenda was constructed to guide the visits. Group and individual interviews were held with key informants in each agency. Executive directors, procurement coordinators, and where appropriate, laboratory personnel were interviewed. In addition, agencies made available samples of their donor case records including all discard cases from 1986.

Based on these visits, a model kidney disposition form was constructed. Data elements were drawn from the records of the most efficient OPOs, UNOS data collection forms and study research objectives. They included organ donor characteristics, timing elements of the donation process, and reasons for organ discard decisions.

Four of the six sites were revisited in the fall to critique the form and insure the clarity of the data collection items. A site visit was also

made to UNOS to familiarize UNOS staff with the process goals of this project and to establish that it would be possible to gather missing data about kidneys imported by OPOs through the UNOS system. UNOS agreed their data collection system would be able to track registered kidneys and produce data missing from the OPO files.

The four OPO sites agreed to pre-test the form for one month in their own agencies to guarantee its applicability.

Kidney disposition study

Fourth, prospective kidney disposition data were collected from cooperating OPOs. The sampling goal was to collect data from 30 percent of the operating OPOs and 50 percent of the kidneys dispersed by the system. Forty-three OPOs were selected to meet these goals. They were chosen for their representativeness in terms of size, discard rate, region, and agency type based on the mail survey data. Of the 43 asked, eight were no longer single agencies but had merged as a consequence of federally mandated regionalization of the OPOs. Twenty-eight OPOs, including three of the new consolidated agencies, agreed to participate in the 12 month prospective study of kidney disposition (January - December 1988). Three OPOs had to withdraw from the study because of competing time demands on their agency staff. Twenty-five agencies provided data for the study. Participating OPOs managed the procurement and distribution of nearly half the kidneys in the U.S. system in 1986.

The kidney disposition form

The kidney disposition form went through six revisions based on consultations and pre-tests with cooperating OPOs. The final instrument contained 32 line items and could be completed in 10 to 15 minutes for each organ donor.

- The survey form contains 32 line items (Appendix A). The first set of data elements concerns donor information (items 1-7), including an OPO donor identification number and a UNOS identification number. The UNOS number was designed to be used to trace a case with missing placement information. In addition, a donor rating scale score (item 6) to be assigned by the procuring agency is included to examine the relationship between quality of donor and timing of placement or discard. Items 8-13 gather information about organ excision and preservation. Item 14 indicates if the organ(s) was locally procured or imported.

- The most detailed section of the instrument is concerned with documenting the steps involved in the procurement and transplant process. A detailed accounting of the procurement process was collected to enable us to identify points of breakdown within the system. Quantification of the time intervals allows us to determine if a directional relationship exists between time and outcome. The variables in this section address the time lapse between kidney removal and implantation (items 9, 15, 16, 17, 29, 30), the number of organ placement calls and time made

(items 18-20, 24-17), the cross matching process and results (items 21, 22, 23), and information about exported kidneys (item 27, 28).

- The last section explores reasons for kidney discard (items 31, 32:1-21). In all, 20 possible reasons for organ discard are listed as well as an "other" category which can be specified. A space for comments is provided for OPO staff to indicate any other information they consider pertinent to the case.

Study OPOs agreed to fill out and return kidney disposition forms on all kidneys passing through their agencies. Completed forms were mailed back monthly to Brandeis. Based on the expectation of 12 monthly returns from 25 agencies, the return rate was 89 percent (277 of 312 possible returns). Complete 12 month data were gathered from 19 OPOs, 11 months of data were collected from 1 agency, 10 months from another, and 6 months from each of the 4 remaining agencies.

Disposition data were collected for 3646 individual kidney cases. In 143 cases, one agency had imported a kidney from another agency in the sample, producing duplicate information. Excluding these duplicate cases, the analyzable dataset includes a total of 3503 kidneys. These represent between 45 and 50 percent of all the cadaveric kidneys procured in 1988.

Telephone inquiry

A fifth source of data was a telephone inquiry completed for the 25 cooperating agencies (Appendix A). The data were gathered to clarify agency specific information regarding tissue typing and crossmatching practices, local and regional sharing agreements, and the agency's relationship with the United Network of Organ Sharing (UNOS).

Validation site visits

Finally, the sixth data source included a series of follow-up site visits with selected study participants to examine closely that agency's performance in comparison with national disposition study indicators. Agencies were visited that were most effective in maximizing the disposition of organs and minimizing organ wastage.

Strengths and limitations

The National Kidney Disposition Study data represent the most comprehensive body of information available about the process of organ procurement and the causes of organ discard in the United States. The 25 OPOs in the study were extremely cooperative and willingly completed the study forms in spite of the other burdensome data reporting requirements imposed on them by the increasingly regulated procurement system. By and large, data were regularly and carefully reported. Repeated telephone contact with the OPOs provided opportunities to clarify any problems agency staff had in completing the forms. Any inconsistencies identified during regular edit checks were clarified by OPO staff who went back to their original records to verify their reports.

One limitation of the study is a high rate of missing data regarding organ placement calls. For about 20 percent of the cases, data were missing on items documenting timing of these calls. Data for these questions were especially likely to be absent for imported kidneys that originated in other agencies. We have addressed these shortcomings by excluding variables from later analyses where we felt insufficient data were present to create a clear picture of the procurement process.

A second limitation should be noted for the subjective donor rating scale data. Although we believe this information is useful because more OPOs are thought to be procuring 'marginal' donors, there is no standard definition of marginal. OPOs rated donors as optimal, satisfactory, or marginal based on their own assessments. In addition, the rating was supposed to have applied to the donor's condition prior to the nephrectomy, but in some cases it may have been influenced by nephrectomy results or the final procurement outcome. Thus, rating scale data should be interpreted with caution.

The most serious limitation of the study is the unidentified fate of 61 kidneys procured but with an unknown outcome. OPOs reported the procurement of these organs but were unable to report if they were transplanted or discarded. The organs were directly exported from their agencies (N=10) or exported through UNOS. Repeated attempts by the OPOs to contact UNOS for 51 kidneys with known UNOS identifiers or the importing agencies were unable to identify the outcomes. Direct requests of UNOS by the Brandeis staff also were unable to produce the records. Although these kidneys represent less than two percent of all the kidneys followed in the study, they might increase the number of discarded organs by as much as 28 percent (51/181). The scarcity of donor organs and the cost of kidney acquisition make this a serious shortcoming of a study examining wastage rates.

Chapter 3

KIDNEY DISPOSITION IN THE U.S.

Kidney discards

Of the 3503 kidney dispositions analyzed in this study, 3,261 were reported transplanted, 181 were discarded, and 61 had unknown outcomes. Excluding kidneys with an unknown outcome from the discard calculation, the average discard rate for OPOs surveyed was 5.2 percent. Assuming that some of the 61 kidneys procured but with unknown outcomes were also discarded, the discard rate could be as high as 6.9 percent. When this kidney wastage study was proposed in 1985, estimates of kidneys procured but not transplanted ranged from 10 to 20 percent. More recent data from HCFA indicate a steady decline in reported wastage from a high of 20.5 percent in 1981 to a low of 4.5 percent in 1988.[13] The evidence indicates that kidney wastage has decreased. It is our opinion that decreases in kidney wastage over the past 10 years are most likely due to 4 factors: changes in the definition of a discard, variations in donor eligibility criteria, improved ability to make surgical repairs to damaged kidneys, and increased efficiency of the national organ sharing system.

Definitions of discard

While wastage appears to have decreased, differences in discard definitions and OPO perceptions that it is important to report low wastage may be causing an underestimation of the problem. Results from the telephone survey and site visit interviews indicate that OPOs differentially report wastage. While more than two-thirds define a discard as a kidney that has been removed from the body of the donor (69 percent), 18 percent have broader criteria (donor entered operating room, 3 percent; incision was made in donor, 16 percent). Some OPOs have stricter criteria, with 11 percent defining a kidney as discarded only if it was ready for transplant but not used. Table 3:1 displays these results from the telephone survey.

Donor eligibility criteria

Discard rates are also affected by the strictness of criteria for donor eligibility. OPOs with exceptionally low discard rates may achieve these by rejecting any level of risk in potential donors. As will be discussed later, marginal donors do have higher discard rates, but 80 percent of kidneys from these donors are transplanted. Some risk may be acceptable as transplant recipient lists continue to grow.

Surgical repairs

Discards may be decreasing because of better surgical facility in repairing anomalous kidneys. Site visit data indicate that some transplant surgeons will mend kidneys harmed during removal under certain conditions. If they themselves retrieved the organs, if respected peers conducted the nephrectomy, or if they have a waiting recipient in dire need of a kidney they may attempt to salvage an organ. However, OPOs also reported that surgeons were unwilling to export surgically damaged kidneys, preferring to keep their 'mistakes' at home.

Improvements in organ sharing

Discards may also be decreasing because of better organ sharing practices implemented since the formation of the OPTN. While some agencies reported problems interacting with UNOS, the majority (63 percent) call UNOS to place kidneys and only 16 percent reported importing no kidneys placed by UNOS in 1988. Few agencies indicated that no matching recipient was the reason for a kidney discard.

In the following section, a model of kidney disposition is discussed, and reasons for kidney discards are addressed.

Development of the model of the career of a kidney

Based on site visits to OPOs and earlier research about agency activities,[4,14] a model was constructed of the career of a kidney procurement. An earlier model[15] had highlighted the process of donor procurement - i.e., identification of the donor, referral to the OPO, approaching the donor family, donor management and then the actual procurement and organ placement. The model developed for this study focuses more on kidney procurement outcomes.

The model of kidney procurement accepts the definition of the OPO as to what is a procured organ. Site visit discussions indicated that definitions of a procurement and a discard could vary from agency to agency but that most agencies made the same assumptions. The telephone survey of cooperating OPOs revealed that nearly two-thirds (64 percent) of the agencies considered a kidney procured if it had been removed from the body of a donor. In these cases, even if a donor had been referred and had been managed by the OPO staff but was not nephrectomized, the kidneys were not counted for reimbursement or distribution statistics. A similar percentage of OPOs (69 percent) counted kidneys as discarded if they had been removed from a donor but were not transplanted to a recipient.

However, approximately 1 in 6 agencies (16-18 percent) used a looser definition, counting kidneys where surgery had begun but may have stopped before excision. These agencies argued that these kidneys should be counted as procured for reimbursement purposes. In many cases, they believed the procurement had gone smoothly but organ placement had been the problem leading to discard. One in 10 OPOs employed a stricter definition, claiming only those kidneys that had been ready for transplant. This definition lowered both their procurement rate and

their discard rate by eliminating from the count any kidney lost during the early stages of the procurement. Table 3:1 demonstrates the distribution of different definitions of procurement and discard.

Table 3:1

Percent of kidneys from agencies with differing definitions of procurement and discard

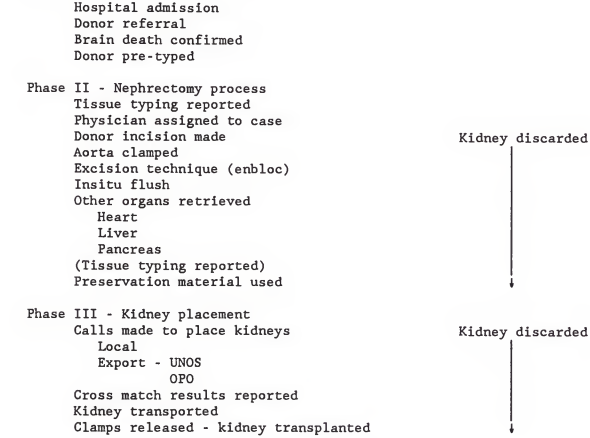
Kidney counted if	Definitions of Procurement	Definitions of Discard
Donor entered O.R.	1.7	2.6
Incision made in donor	17.6	15.9
Kidney removed	63.7	69.4
Kidney removed & preserved	4.9	0.0
Kidney intended for use but not used	11.0	11.0
Missing information	1.1	1.1

Descriptive results from Kidney Disposition Survey

By whatever definition, a kidney procurement goes through three stages - donor identification, the nephrectomy process, and kidney placement. Figure 1 demonstrates the major events in the model and also shows where discard decisions are likely to occur. For the majority of agencies that hold that a kidney removed is a kidney procured, a discard decision could not be made until after the kidneys are excised.

Figure 3-1

Kidney procurement process model in three phases



Donor identification

The identification and referral of a donor in the local area of the OPO is the first step in the kidney procurement model. As the time frame may differ for donors or kidneys from other OPOs, the model for procurement of imported kidneys will be discussed in a later section.[1]

The career of locally procured kidneys occurs in three phases: donor identification and referral, the nephrectomy process, and organ placement leading to transplantation or discard. Key decision points mark each phase. An organ procurement begins with donor identification and referral. For the OPO a local case starts with the referral of a donor to that agency. Most agencies log in the time when they receive a referral call. However, a procurement may begin earlier, either at hospital admission for a donor who enters on life support and shows clinical evidence of being brain-dead or when brain-death is confirmed by the hospital and then a referral call is made to the OPO. The model of a kidney procurement allows for different start times, and the data show a considerable range of referral conditions. The majority of local kidney referrals come before the brain death declaration, but a third occur after declaration (see Table 3:2).

Table 3:2

Order of referral and brain death for all kidneys locally procured

Referral times	Number	Percent
Referral before brain death confirmed	1391	55.0
Referral after brain death confirmed	835	33.0
Referral at the same time brain death is confirmed	304	12.0
Total of locally procured kidneys	2530	100.0

A surprising percentage of kidneys (44.2 percent) were pre-typed in the donor identification and referral stage, before the donor was brought into the operating room (O.R.) for the nephrectomy. While a potential donor's blood group can be readily determined by reading the medical record or using blood drawn for other purposes, pre-typing usually means tissue typing. HLA tissue typing requires donor tissue, and this tissue typing usually takes from four to six hours. Pre-typing considerably

[1] For kidneys that are imported, kidney referral comes via UNOS or the exporting OPO. In many cases, donor referral time information is lost or considered irrelevant. The clock starts with the agency referral of the kidney. The career of these kidneys in the importing OPO begins with the third phase, organ placement.

speeds up the identification of eligible recipients and thus lowers overall organ placement time. This may reduce the incidence of organ discard.

In the identification and referral stage, a medical and brief social history of the donor is taken. Potential donors are screened and excluded for known life styles that may increase the risk of exposure to the human immunodeficiency virus. Factors such as age, sex and race are considered as are cause of death and diagnosis at death (Table 3:3). Most of the time (in 86 percent of the kidney cases) OPOs are willing to rate donors as optimal, satisfactory, or marginal.[2]

[2]No instructions were given to OPOs in assigning these ranks. Instead, agencies were told to categorize by their own internal standards. In some cases, donor rating scales may have been influenced by post-nephrectomy results, leading to some need for caution in interpreting these data.

Table 3:3

Number and percent distribution of procured kidney sample by donor demographic characteristics

Characteristic	Number	Percent distributions
Sex		
Male	2,150	61.4
Female	1,306	37.3
Unreported	(47)	
Total valid cases	3,456	100.0
Race		
Hispanic	281	8.1
Black	341	9.1
White	2,829	81.7
Other	38	1.1
Unknown	(41)	
Total valid cases	3,462	100.00
Age		
Infant - 10 years	393	11.4
11 - 20 years	868	25.1
21 - 30 years	829	24.0
31 - 40 years	570	16.5
41 - 55 years	591	17.1
56 - 70 years	210	6.1
Unknown	(42)	
Total valid cases	3,461	100.0
Cause of death		
MVA	1,236	36.5
Other accident	923	27.3
Homicide	228	6.7
Suicide	308	9.1
Illness	690	20.4
Unknown	(118)	
Total valid cases	3,385	100.0
Diagnosis		
Trauma	1,892	54.9
Cerebral bleeds	1,092	31.7
Brain tumors	31	0.9
Anoxia	281	8.2
Other	151	4.4
Unknown	(56)	
Total valid cases	3,447	100.0

Table 3:3 (continued)

Number and percent distribution of procured kidney sample by donor demographic characteristics

Characteristic	Number	Percent distributions
Donor rating scale		
Optimal donor	1,207	40.0
Satisfactory donor	1,478	49.0
Marginal donor	333	11.0
Unknown	(485)	
Total valid cases	3,018	100.0
Donor pretyped		
Yes	1,314	44.2
No	1,660	55.8
Unknown	(529)	
Total valid cases	2,976	100.0

*These numbers and percents do not total because several donated more than two organs, i.e., heart and liver.

Most of the kidneys in the study reported here came from donors who were likely to be white and male. Half of the donors were between the ages of 11 and 30. Kidneys from pediatric donors, defined here as those ten years old and less, represent a small proportion of kidneys (less than 12 percent). Most donor kidneys are given by people in their teens or twenties. However, there is a surprising 6 percent of donations from people over 55, and even some donations from people over 65 (n=19). Most donors had died of trauma-related diagnoses due to motor vehicle accidents. OPOs assessed the majority of donors as satisfactory candidates for donation, and a large proportion were deemed optimal. A small percentage (11 percent) were classified as marginal.

It is interesting to more closely examine the distributional information in Table 3:3 because it contradicts some of the common beliefs about donors. For example, black and hispanic donors are thought to be vastly underrepresented in donor pools (Perez et al.). Statistics here demonstrate that they indeed are underrepresented but considerable percentages do donate. Twelve percent of the general population is black and 13 percent is hispanic. However, 9 percent of kidneys in this sample come from donors reported as black, and 8 percent are from donors of hispanic origin.

To create a time frame for the donor identification and referral stage of the procurement process, three timing intervals have been calculated. The data used to develop these intervals are from selected locally procured kidneys, 1398 cases for which there are complete data. The three timing intervals are

- the time from hospital admission to confirmed brain death declaration;
- the time from brain death declaration to the time the aorta is clamped shut, indicating the beginning of cold ischemic time and excision time; and
- an inclusive interval from hospital admission to aorta clamp time.

The statistically significant differences between transplant and discard outcomes shown in Table 3:4 indicate that kidneys which are later discarded have shorter time spans in each interval than do transplanted kidneys. This may be due to discarded kidneys coming from a donor identified as unstable and rushed to the O.R. for organ excision.

Table 3:4

Timing intervals (in hours), t-test values and significance levels for selected locally procured kidneys by outcome in donor referral phase

Timing interval	Trans plant	Disc card	T-value	Sig level	N
Admission to brain death	61.7	44.5	3.05	.001	1398
Brain death to clamp	10.2	7.7	3.41	.0001	1398
Admission to clamp	71.9	52.4	3.45	.0001	1398

The nephrectomy

Most often a transplant surgeon performed the nephrectomy. However, 11 percent of the time kidneys were excised by local surgeons, and residents or fellows were responsible for less than 6 percent of the kidney procurements. Typically, kidneys were removed en bloc and insitu flush was the preferred beginning of organ preservation.

The most common preservation medium was slush, but perfusion, which had been declining in popularity, was used 11 percent of the time by itself and an additional 6 percent in combination with slush. The rise in the use of perfusion may indicate attempts to preserve increasing numbers of kidneys from very young donors, kidneys that will travel long distances, or kidneys that appear marginal and are tested for viability on the perfusion machine. Multiorgan procurement, excising kidneys and other organs, characterized almost half of the procurements with hearts being the most commonly procured along with kidneys. Table 3:5 displays these results.

Table 3:5

Number and percent distribution of procured kidney sample by nephrectomy characteristics

Characteristic	Number	Percent distributions
Nephrectomy performed by		
Transplant surgeon	2,645	82.2
Fellow	174	5.4
Resident	14	0.4
Local surgeon	353	11.0
Other	32	1.0
Unknown	(285)	
Total valid cases	3,218	100.0
Kidneys taken en bloc		
Yes	2,836	87.9
No	392	12.1
Unknown	(275)	
Total valid cases	3,228	100.0
Insitu flush used		
Yes	2,961	92.5
No	239	7.5
Unknown	(303)	
Total valid cases	3,200	100.0
Type of preservation used		
Slush	2,778	83.1
Perfusion	364	10.9
Both	210	6.0
Unknown	(160)	
Total valid cases	3,343	100.0
Multiorgan donation - kidney and*		
Heart donation	1,616	46.1
Liver donation	1,388	39.6
Pancreas donation	545	15.6

Kidney placement and procurement outcome

Most kidneys that were placed were transplanted. Out of the 3,503 kidneys, 181 were reported as discarded - only 5.2 percent. A more troublesome category is represented by the 61 kidneys for which the outcome is unknown. Neither the procuring OPO nor UNOS could account for the disposition of these kidneys. Considering the tremendous demand for cadaveric kidneys, the acquisition cost of more than $9,500[16] for each procured kidney, and the cost of maintaining an ESRD patient on dialysis, the causes of this data lacuna warrant further analysis.

Table 3:6

Kidney Disposition Outcomes

Characteristic	Number	Percent distributions
All kidneys outcome	3,503	100.0
Transplanted	3,261	93.1
Discarded	181	5.2
Unknown outcome	61	1.7

Reasons given by OPOs for kidney discards

More than 76 percent of kidney discards are reported to be due to 5 major causes. Table 3:6 shows the distribution of primary and secondary reasons reported for kidney discards.

Table 3:7

Primary and secondary reasons for kidney discard

Reasons	Primary		Secondary	
	Number	Percent	Number	Percent
Total	181	100.0	40	100.0
Donor/organ pathology	52	28.9	4	10.0
Anatomic abnormality	30	16.7	6	15.0
Surgical complication	20	11.1	6	15.0
Positive cultures	19	10.6	0	
Organ injury prior to nephrectomy	16	8.9	2	5.0
Preservation error	15	8.2	5	12.5
Donor size too small	12	6.7	0	
No suitable tissue match	0		2	5.0
No negative crossmatch	0		4	10.0
Transportation problem	0		1	2.5
Other reasons	17	8.9	2	15.0

The most frequently reported cause of discard is donor or organ pathology, representing over a quarter of all discard cases. Both this reason and the next, anatomical abnormality, represent information not discovered until the time of the nephrectomy. Anatomical abnormalities were cited for 17 percent of the discarded kidneys (30/181 kidneys discarded) and 0.86 percent of all kidneys procured (30/3503 kidneys procured). Anatomical abnormalities can sometimes be surgically corrected for some recipients but not for others.

The reported incidence of anatomic abnormalities listed in Table 1:1 in Chapter 1 shows anomalies of renal vasculature to be quite common, occurring in 29 percent of all people (2,890/10,000). However, surgeons commonly repair kidneys with such problems as multiple or accessory arteries in transplantation.

Anatomic abnormalities that are likely to cause discard appear to be much rarer, ranging from .005 percent (0.5/10,000) to .26 percent (25.6/10,000). It would seem that anatomic abnormalities are cited about four times more frequently as reasons for discard than they would appear to be likely to occur in the population. However, the disparity between the incidence data and the sample data may be due to the small number of discarded kidneys reported upon here.

Surgical complications are given as the third most frequent primary reason for kidney discard. They represent 11 percent of primary reasons and 15 percent of secondary reasons. OPO staff report that surgical complications are most often due to technical errors by transplant surgeons, technical or judgement errors by inexperienced surgeons or surgical damage to a kidney resulting from a multiorgan procurement when another organ is removed. OPOs also report that a transplant surgeon may use kidneys damaged by himself or his colleagues locally but surgical mistakes are rarely exported or imported.

The fourth cause of wastage are kidneys discarded when laboratory results of positive cultures are reported for donors who have already been taken to the operating room. The decision to discard a kidney is usually unequivocal in the case of positive culture reports, but site visit interviews indicated opinions may vary regarding hepatitis results. The fifth cause of discards are kidneys found to have been injured in the event leading to the donor's death but not discovered until nephrectomy. However, OPOs report that not all injured organs are discarded. The decision to discard may be mediated by a transplant surgeons' willingness to try to repair an injured organ.

Two other causes cited for kidney discard decisions include preservation errors and 'donor size too small.' Together these represent 14.9 percent of primary reasons for all discards and may occur when preservation efforts cannot keep a kidney viable until a suitable recipient is identified or when a suitably small (generally young) recipient cannot be found in time.

Other primary reasons given for discarding kidneys, amounting to less than 9 percent of all primary reasons for discard, have to with donor arrest in the operating room (n=6), a positive HIV report (n=2), no matching blood type recipient (n=1), a contaminated organ (n=1), and other non-specified reasons (n=6).

None of the OPOs cited delays in kidney placement as the primary cause of kidney discard. Yet a closer examination of primary and secondary discard reasons does

show that the length of time needed to find a suitable recipient for a kidney may result in a kidney discard. Twelve kidneys had secondary discard reasons reported which point to difficulty finding a recipient; i.e., other preservation problems, no negative crossmatch, no suitable tissue match, and transportation problems

Organ sharing characteristics

Organ placement and sharing practices have long been a focus of analysis of the effectiveness of the U.S. organ procurement system. Among agencies reporting for the 1988 National Kidney Disposition Study, nearly three quarters of all kidneys procured were kept by the locally procuring OPO (Table 3:7). The remainder were shared: 14 percent were exported to other agencies, and 12.5 percent were imported from them directly or via UNOS. Less than one percent were re-exported.

Table 3:8

Number and percent distribution of procured kidney sample by organ-sharing characteristics and by outcome

Characteristic	Number	Percent distributions
All kidneys	3,503	100.0
Procured locally and kept	2,547	72.7
Procured locally and exported	490	14.0
Imported and kept	439	12.5
Imported and re-exported	27	0.03
Kidneys procured locally	3,037	100.0
Kept	2,547	83.6
Exported	490	16.1
Local kidneys kept	2,547	100.0
Transplanted	2,384	93.6
Discarded	146	5.7
Unknown outcome	17	0.7
Local kidneys exported	490	100.0
Transplanted	439	89.6
Discarded	19	3.9
Unknown outcome	32	6.5
Kidneys imported by OPO	466	100.0
Kept	439	94.2
Re-exported	27	5.8
Imported kidneys kept	439	100.0
Transplanted	422	96.1
Discarded	13	3.0
Unknown outcome	4	0.9
Imported kidneys re-exported	27	100.0
Transplanted	16	59.3
Discarded	3	11.1
Unknown outcome	8	30.0

Discard rates vary considerably for organs kept and those shared. Overall, 5.2 percent of procured kidneys were discarded. Locally, the discard percentage rose to 5.7 percent, while the discard rate for shared organs ranged between 3.0 to 3.9 percent. Among organs re-exported the discard percentage increased to 11 percent, but as this represents only 3 kidneys, this percentage is not a reliable indicator of discards in this category. These findings indicate that kidney discards are more likely to occur at the local level. Further analysis of timing intervals is necessary to more clearly delineate the effects of sharing and these are discussed in chapter 6.

Chapter 4

THE IMPACT OF DONOR CHARACTERISTICS, PROCUREMENT EVENTS, AND ORGAN SHARING ON KIDNEY DISCARD

Donor characteristics

While approximately 5 percent of all kidneys are discarded, and 2 percent have unknown outcomes, there are several statistically significant differences in discard percentages by donor characteristics (Table 4:1). Not surprisingly,* discards are most frequent for kidneys from donors who are rated as marginal by organ procurement coordinators. For the donors of these kidneys, the procurement enterprise has been risky from its inception. However, discussions with OPO staff indicate that most often the judgment was made to proceed with the procurement because of the chance that the procurement might result in a viable transplant, and the known skill of the medical personnel carrying out the surgeries.

Table 4:1

Selected percent distributions of transplanted and discarded kidneys by donor characteristics

	Total Kidneys	Trans-planted Kidneys	Discarded Kidneys	Un-known Outcome	Chi square Statistic	p-value
	Percent Distribution					
All kidneys	100	93	5	2	--	--
Marginal kidneys	11	80	20	--	56.94	.0001
Cause of death:illness	20	89	10	1	28.76	.0001
Pediatric kidneys	11	90	8	2	7.14	.0076
Minority kidneys	18	92	6	1	1.74	.1873
Donor pretyped	44	96	3	1	9.92	.0016

Kidneys from donors whose cause of death was reported to be an illness, usually a cerebral bleed, were twice as likely to be discarded as kidneys from all donors. Kidneys from donors who were children were more likely to be discarded than adult kidneys. Kidneys that were pre-typed were more likely to result in a transplant than non-pretyped kidneys. Kidneys from minority donors were not more likely to be discarded.

*OPOs were instructed to rate donors as optimal, satisfactory, or marginal according to their "general physical condition previous to death and other factors [agencies] take into account in considering placement of the organs." [See Appendix A: National Kidney Disposition Study Instructions, Disposition Form Line-by-Line Instructions, Line 6.]

Table 4:2

Selected percent distributions of transplanted and discarded kidneys by procedural characteristics

	Total Kidneys	Trans-planted Kidneys	Discarded Kidneys	Un-known Outcome	Chi square Statistic	p-value
	Percent Distribution					
All kidneys	100	93	5	2	--	--
Local surgeon	11	91	8	2	7.06	.0079
Not enbloc	12	98	2	--	15.48	.0001
No insitu flush	8	87	12	1	14.60	.0001
Heart donated	46	96	3	1	25.00	.0001
Liver donated	40	96	3	1	18.54	.0001

Five factors have a statistically significant impact on kidney discard in the nephrectomy stage of organ procurement (Table 4:2). Where local surgeons perform the nephrectomy, in 11 percent of the cases, 8 percent of the kidneys are discarded. The statistical significance of this finding suggests better training of procurement surgeons would reduce organ wastage. Where kidneys are not taken en bloc, the chances of discard appear lower, and where insitu flush is not the method of preservation discards increase. Kidneys from multiorgan donors are less likely to result in discard. However, a multiorgan procurement is most often carried out where there is the best chance of success in retrieving and placing the organs.

Table 4:3

Selected percent distributions of transplanted and discarded kidneys by organ sharing characteristics

	Total Kidneys	Trans-planted Kidneys	Discarded Kidneys	Un-known Outcome	Chi square Statistic	p-value
	Percent Distribution					
All kidneys	100	93	5	2	--	--
Imported organ	13	94	3	3	0.01	.9740
Exported organ	15	88	4	8	65.08	.0001

In the third stage, kidney placement, the relationship between events and discard are more complicated. Lack of data for 8 percent of exported organs make it difficult to assess thoroughly causes of discard for this group. As discussed earlier, long intervals between nephrectomy and the placement decision for shared organs may result in discards in some cases but not in others.

There is no statistical difference between imported and locally procured organs in terms of discard (Table 4:3). Exported organs reveal a lower percentage of transplanted organs not necessarily because of a higher discard rate but because outcomes for these organs are the most likely to be "unknown."

Chapter 5

KIDNEY DISCARDS FROM SPECIAL POPULATIONS: MINORITY, PEDIATRIC, AND MARGINAL DONORS

Understanding organ wastage from special populations was one goal of this study. In the previous chapter, kidneys from pediatric and marginal donors were shown to have statistically significant higher wastage rates than kidneys from adult and non-marginal donors. Wastage rates of kidneys from minority donors were clearly revealed to be no higher than non-minority donors.

Kidneys from minority donors

The following data further document that while transplanted kidneys from minority donors have characteristics that differ in some ways from non-minority donors, there are no statistically significant differences in discarded kidneys from minority donors (Table 5:1). Kidneys from minority donors comprise 18 percent of all kidneys procured in this study, 92 percent are transplanted and 6 percent are discarded. Kidneys from minority donors were identified by OPO staff from hospital records specifying the race/ethnicity of the donor kidney with 8 percent (n=281) identified as hispanic, 9 percent as black (n=314), and 1 (n=38) percent as another race/ethnicity.

Table 5:1

Selected percent distributions of transplanted and discarded kidneys for minority and non-minority kidneys by donor, procedural and organizational characteristics

	Total Kidneys	Minority Kidneys	Non-Minority Kidneys	Chi square Statistic	p-value
Number of cases	3462	633	2829	--	--
		Percent Distribution			
Total kidneys	100	18	82		
Transplanted kidneys	94	92	94	1.73	.1873
Donor characteristics					
Female	38	32	39	10.34	.0013
Homicide	7	18	4	1.79	.1810
Marginal	9	8	10	1.28	.2577
Procedural characteristics					
Insitu flush	93	91	94	5.11	.0238
Heart donated	47	43	48	6.26	.0124
Liver donated	41	34	42	12.10	.0005
Discarded kidneys	5	6	5	1.73	.1873
Donor characteristics					
Homicide	6	17	2	1.95	.1627
Marginal	43	55	39	2.44	.1184
Procedural characteristics					
Heart donated	29	41	26	3.37	.0663
Organizational characteristics					
Imported	8	3	10	2.11	.1461

Transplanted kidneys from minority donors have 2 different donor characteristics: they are more likely to have come from donors who were male and who died of a homicide. There are also significant differences in nephrectomy procedures. Kidneys from minority donors were less likely to be perfused insitu or to have been part of a multiorgan procurement.

There are no significant differences in donor, procedural or organizational characteristics between discarded kidneys from minority and non-minority donors. Although there is a higher percentage of marginal donors of discarded kidneys, this difference does not reach statistical significance. Fewer minority kidneys were imported, but this is also not statistically significant.

Table 5:2

Selected percent distributions of discarded kidneys for minority and non-minority kidneys by reasons for discard

	Total Kidneys	Minority Kidneys	Non-Minority Kidneys	Chi square Statistic	p-value
Number of cases	171	39	132		
		Percent distributions			
Total Kidneys	100	23	77		
Reasons for Discard					
Donor/organ pathology	29	15	34		
Anatomic abnormality	17	5	20		
Surgical complications	12	15	11		
Prior organ injury	9	13	8		
Positive culture	9	21	5		
Preservation problem	9	8	9		
Too small	6	10	6		
Positive HIV	1	5	0		
Other reasons	8	8	7	0.17	.6801

An analysis of the reasons for discard of minority kidneys reveals some large percentage differences, but these differences also do not reach levels of statistical significance (Table 5:2). The ranking of discard reasons differs for kidneys from minority and non-minority donors. While anatomic abnormalities are the second most frequent cause of discard for non-minority kidneys, they are a distant sixth for minority kidneys. Twice as many non-minority donor kidneys were discarded for reasons of donor/organ pathology while prior organ injury more often went undetected in minority donors. There were four times as many positive cultures on discarded kidneys from minority donors than from non-minority donors.

Kidneys from pediatric donors

Kidneys from pediatric donors represent 11 percent of kidneys (333 kidneys) procured and allocated by organ procurement organizations participating in the 1988 National Kidney Disposition Study. Pediatric kidneys were identified as organs coming from donors ten years of age or younger.

Pediatric kidneys are significantly more likely to be discarded than are adult kidneys. Whereas 5 percent of all kidneys were wasted in 1988, 8 percent of pediatric kidneys were not used (Table 5:3). Both transplanted and discarded kidneys from pediatric donors differed from adult donors by donor, procedural, and organizational characteristics.

Among kidneys that are transplanted from pediatric donors sex and cause of death differ for pediatric kidneys. Among adult donors, males are overrepresented. However, pediatric kidneys are more likely to come from female donors. Not surprisingly, another difference between adult and pediatric kidneys is in cause of death. Accidents, other than motor vehicle accidents, are the second most frequent cause of death leading to donation. Among children, these accidents are the primary cause. Donors of pediatric kidneys are less likely to be rated as marginal than are adult donors. Perhaps pediatric donor candidates are selected to reduce the chances of failure in organ procurement and placement.

Clinical difficulties account for several statistically significant differences between procuring pediatric and adult kidneys. Transplant surgeons are more likely to perform the nephrectomy than they are in adult procurements, but this difference does not reach levels of statistical significance. Pediatric kidneys are much more likely to be procured enbloc. Pediatric donors are considerably less likely to be heart donors, but reflecting the demand for pediatric livers, they are more likely to be liver donors.

In spite of precautions taken by procurement personnel, discards from pediatric donors are significantly higher than among adult donors. Higher wastage rates among pediatric kidneys are due to two main factors having to do with inherent difficulties of pediatric procurement: technical and placement difficulties.

Table 5:3

Selected percent distributions of transplanted and discarded kidneys for pediatric and adult kidneys by donor, procedural and organizational characteristics

	Total Kidneys	Pediatric Kidneys	Adult Kidneys	Chi square Statistic	p-value
Number of cases	3461	393	3078	--	--
		Percent Distribution			
Transplanted kidneys	94	90	94	7.14	.0076
Donor characteristics					
Female donors	38	47	37	14.93	.0001
Accidents, not MVA	28	40	26	16.46	.0001
Marginal rating	9	4	10	11.14	.0008
Procedural characteristics					
Heart donor	47	29	50	51.79	.0001
Liver donor	41	59	39	52.18	.0001
En bloc	87	93	87	10.29	.0013
Transplant surgeon	83	87	82	3.14	.0764
Organizational characteristics					
Imported organ	13	29	12	78.81	.0001
Exported organ	14	23	13	30.02	.0001
Discarded kidneys	5	8	5	7.14	.0076
Donor characteristics					
Marginal rating	43	12	49	12.10	.0005
Procedural characteristics					
Liver donor	25	59	17	25.04	.0001
Insitu flush	80	96	77	4.93	.0264
Organizational characteristics					
Imported organ	9	19	7	4.52	.0335
Exported organ	12	41	6	28.61	.0001

The reasons given for discard of pediatric kidneys also differ significantly (Table 5:4). Most often pediatric kidneys are discarded because they are too small. Perhaps related to this are the high percentage of surgical complications cited as the reason for discard of pediatric kidneys. The nephrectomy of pediatric organs is much more difficult technically because of the small size of the donor. Another interesting difference is the absence of prior donor or organ pathology cited as the reason for discard. This may be due to the high percentage of pediatric donors due to accidental deaths rather than deaths caused by illness.

Table 5:4

Selected percent distributions of discarded kidneys for pediatric and adult kidneys by reasons for discard

	Total Kidneys	Pediatric Kidneys	Adult Kidneys	Chi square Statistic	p-value
Number of cases	177	32	145		
	Percent distributions				
Total Kidneys	100	18	82		
Reasons for Discard					
Donor/organ pathology	29	0	36		
Anatomic abnormality	16	16	16		
Surgical complications	11	22	9		
Prior organ injury	9	6	9		
Positive culture	11	3	12		
Preservation problem	9	6	9		
Too small	7	38	0		
Positive HIV	1	0	1		
Other reasons	7	9	8	14.42	.0002

Kidneys from marginal donors

The kidneys that are transplanted from marginal donors are less likely to come from pediatric donors or from donors that are pre-typed. The perfusion method of preservation is more likely to be used, and marginal donors are less frequently multiorgan donors. Kidneys from marginal donors are also less likely to be imported (Table 5:5).

Table 5:5

Selected percent distributions of transplanted and discarded kidneys for marginal and non-marginal kidneys by donor, procedural and organizational characteristics

	Total Kidneys	Marginal Kidneys	Non-Marginal Kidneys	Chi square Statistic	p-value
Number of cases	3018	333	2685	--	--
		Percent Distribution			
Total kidneys	100	11	89		
Transplanted kidneys	93	80	95	56.94	.0001
Donor characteristics					
Pediatric donors	11	5	11	11.14	.0008
Donor pre-typed	39	26	41	16.22	.0001
Procedural characteristics					
Perfusion	12	18	12	11.96	.0005
Heart donor	48	27	50	51.80	.0001
Liver donor	40	16	43	72.20	.0001
Organizational characteristics					
Import	12	8	12	4.21	.0402
Discarded kidneys	5	20	4	56.94	.0001
Donor characteristics					
Pediatric donors	16	4	25	12.10	.0004
Minority donors	21	27	17	2.44	.1184
Cause of death:illness	41	45	38	3.35	.0671
Procedural characteristics					
Insitu flush	79	63	89	13.89	.0002
Perfusion	14	30	6	11.09	.0009
Heart donor	29	19	37	5.96	.0147
Liver donor	22	3	36	24.70	.0001
Organizational characteristics					
Export	13	0	22	17.15	.0001

Organ discards from marginal donors are more likely to come from adult than pediatric donors and illness is more often the cause of death than trauma among marginal donors. Perfusion is much more often used to preserve kidneys from marginal donors, perhaps to stave off discard. No exported kidneys that resulted in a discard outcome were known to be from marginal donors. This reinforces OPO's staff comments that potential mistakes are kept at home.

Table 5:6

Selected percent distributions of discarded kidneys for marginal and non-marginal kidneys by reasons for discard

	Total Kidneys	Marginal Kidneys	Non-Marginal Kidneys	Chi square Statistic	p-value
Number of cases	162	68	94		
		Percent distributions			
Total Kidneys	100	42	58		
Reasons for discard					
Donor/organ pathology	32	44	23		
Anatomic abnormality	17	6	26		
Surgical complications	11	3	16		
Prior organ injury	7	9	5		
Positive culture	9	13	6		
Preservation problem	9	13	6		
Too small	6	3	9		
Positive HIV	1	3	0		
Other reasons	8	6	9	4.15	.0416

Examining the reasons for discards for kidneys from marginal donors reveals that anatomical abnormalities and surgical complications were less likely to be given as the reason for discard (Table 5:6). Instead, donor or organ pathology and the reports of positive cultures, perhaps suspected in the designation of the donor as marginal, were the most likely cause of discard.

The analysis of organ discard decisions of kidneys from special populations such as minority, pediatric and marginal donors reveals some interesting findings. First, discards are not more likely to come from minority donors than white donors. Second, kidneys from pediatric donors are most likely to be discarded due to the small size of the donors and the surgical complications ensuing from trying to procure them. Third, kidney wastage from donors rated as marginal by the procuring OPO is surprisingly limited. Although it far exceeds wastage from other groups, about 80 percent of kidneys retrieved from marginal donors result in a transplant.

Chapter 6

PROCESS AND ORGANIZATION

Background Description of OPOs

About 50 percent of the kidneys procured in the nation during our study period are included in our data, however only about 25 percent of certified OPOs are part of the study. This was the result on an intentional strategy to maximize the amount of organ specific data we could obtain within our resource constraints. However, it does mean that OPO respondents are not typical of the OPO system as a whole- although they are typical in terms of key factor such as wastage rates.

Table 6:1

Responding OPO Characteristics

Variable	Median
Number of organs procured	95.0
Percent locally procured and used	73.9
Percent imported	9.9
Percent exported	18.8

As the 95 kidney number indicates, our respondents are substantially larger than the average OPO. These data also indicate that shared organs, while down from their highest levels, still represent over 25 percent of the kidneys used in the U.S. (Because we have only a sample of the organ procurement system there is some double counting of exported and imported organs.)

The placement of procured organs remains a labor intensive process. Overall it required between two and three calls to place every kidney used locally, and an additional one or two to place organs at another OPO. This relatively small additional effort may reflect the widespread use of UNOS as an intermediary in organ export.

Table 6:2

Placement Process

Variable	Mean
Number of local call made	2.3
Number of export call made	1.5
Percent using UNOS to place exported organs	72.1
Percent using UNOS rules to place local organs	69.9
Number of local negative cross matches	15.4

There was a large difference between the mean number of local negative cross-matches and the median number (15.4 vs 2.95). As each suitable organ after the first becomes increasingly irrelevant the median is probably a more meaningful figure. In general, we would expect kidney exports to be inversely related to the number of local negative cross-matches. Finally, notice that only 69.9 percent of respondents state that they are using UNOS rules to place local organs.

Wastage rates among local and shared organs

Over 73 percent of all kidneys never leave the locality in which they are procured. Local processes and decision rules therefore predominate in the nation's organ procurement and distribution system. In our sample 80.7 percent of all organs discarded were discarded by the OPO which procured them. (This is, in effect, what we mean when we talk about "local" discards") Not only are most discarded organs discarded locally but the discard rate for local organs is significantly higher than for organs that have been shared between OPOs. As Table 6:3 indicates 5.8 percent of local organs are discarded. The discard rate for shared organs is lower.

Table 6:3

Local vs Shared Discard Rates

	Locals	Shared	Total
Discard Rate	5.8	3.8	5.3
N	2530	912	3442

Chi-Squared Significant at .02

Table 6:4 indicates, the central reason that a larger percentage of local than of shared organs are discarded. Almost 54 percent of all organs discarded are discarded within 10 hours of being procured. Most of these organs are deemed unsuitable before they could reasonably be offered to another OPO. If one considers only those organs discarded 10 or more hours post-nephrectomy we find that shared organs are almost 50 percent more likely to be discarded than are organs locally used.

Table 6:4

Discard Decision in Hours Post-Nephrectomy

	Local	Shared	Total
No Nephrectomy	13.6	0.0	11.2
Discarded by 10 hrs	48.2	8.7	41.4
Discarded after 10 hrs	38.2	91.3	47.4

Some categories of shared organs are more likely to be discarded than others. As Table 6:5 shows, organs that are exported more than once are far more likely never to be transplanted. (Although the number of such organs is very small.) For the system as a whole "imports" and "exports" are the same organs- counted twice. In our sample this is not the case as there is a flow of organ into and out of the sample. We have excluded double counted organs.

Table 6:5

Shared Organ Discards

	Shared	Imports	Exports	Rw-Exports
Discard Rate	3.8	3.0	4.1	15.8
N	912	435	458	19

Process and Discard

There were various factors regarding the timing and sequencing of critical steps in the procurement process that may explain discard rates. Three timing variables may be relevant for the ultimate disposition of donated organs: admission time, time of brain-death declaration and time of nephrectomy. Table 6:6 indicates that longer intervals were characteristic of successfully transplanted organs than of organs finally discarded. The average donor spent two to two and a half days in the hospital until brain-death was declared and another 8 or 10 hours were spent between the declaration of death and the nephrectomy. In all cases donors whose organs

were transplanted spent more time than those whose organs were ultimately discarded. On average the entire process took about 20 hours longer for donors whose organs were used, almost a day longer in the hospital. This is contrary to conventional wisdom which teaches that longer hospital stays render donors less suitable.

Table 6:6

Timing Intervals in Hours

	Tx	Discard
Admission to B-D	61.7	44.6
B-D to Clamp	10.2	7.7
Admission to Clamp	71.9	52.4

All differences statistically significant

We also found a difference between transplanted and discarded cases in terms of time between referral and brain-death. This is a statistically non-significant difference. However, differences were found in terms of sequencing the referral and brain-death declaration. Most OPOs urge hospitals to refer potential donors to them as early in the process as possible. They feel that the process is facilitated if they are brought in before the declaration of death. Our data show that the majority of cases are referred to OPOs before brain death is confirmed.

Table 6:7

Referral and Brain Death Declaration

	Tx	Discard	Total
Referral before	55.1 %	53.4 %	55.0 %
Referral after B-D	32.6 %	39.7 %	33.0 %
Referral at Same Time	12.3 %	6.8 %	12.0%
Time Between Referral and B-D	8.3 hrs	7.1 hrs	

Fifty-five percent of the time the referral and declaration of death occur in the sequence preferred by OPOs (Table 6:7). One of the reasons many OPOs prefer early referral is that when a referral precedes the declaration of death donor pre-typing is possible.

Chapter 7

MULTIVARIATE ANALYSIS OF KIDNEY PROCUREMENT OUTCOMES

Kidney wastage has been shown to be the result of many complex events in an organ procurement. Chief among them are donor characteristics, the timing of the procurement, the nephrectomy process, and OPO organizational variables. Multivariate regression analysis is a useful tool for examining the effects of these events together. Regressions were conducted for locally procured and kept kidneys, and kidneys from marginal, pediatric, and minority donors.

Analytic decisions made regarding the variables chosen for the multivariate analysis reflected judgments about the best way to use the data. Because of missing data for shared organs, the analysis of the largest group of kidney disposition decisions is limited to those that were locally procured and kept within the OPO. However, for the analyses of the discard decisions among special populations - kidneys from pediatric, marginal and minority donors - both local and imported and exported kidneys were included. This decision was made to examine as many cases as possible in these smaller subsamples.

The final model arrived at for analysis includes variables shown to have statistically significant effects on kidney disposition for kidneys locally procured and kept. These include donor characteristics, timing from admission to kidney excision (clamp), features of the nephrectomy, and OPO organizational variables.

Variables were selected for the model through several methods. Prior bivariate analyses such as tabular analyses, t-tests, and Pearson Correlation tests were used to identify predictive variables. In addition, variables were chosen to test hypotheses regarding discard decisions. The final selection of variables for the model was a consequence of these prior decisions and the desire to create the most statistically efficient model.

The variables selected for the multivariate model differ in some ways from those in the bivariate analyses. The variable measuring a marginal donor rating was excluded from the analysis because it is likely the rating was assigned after the kidney was discarded when the OPO representative completed the kidney disposition form. Therefore, the rating cannot be said to predict discard. To assess the variables predicting discard among kidneys from donors assigned the marginal label, a separate regression is run and discussed later.

For the regression analyses, there is no variable measuring age of less than 10 years, the variable used earlier to identify pediatric donors. Instead a variable was created indicating kidneys from donors of less than 40 pounds, and this was used as a proxy for pediatric donors. OPO staff

have said that it is the combination of age and size that makes procuring and transplant pediatric kidneys difficult. Using the weight variable also allowed us to keep the age variable as a continuous measure of the effect of age on discard decisions.

The variables arrived at to measure donor characteristics include donor age, weight of less than 40 pounds, white race, illness as cause of death, and the rare AB blood type. OPO staff had indicated that it is extremely difficult to place organs from an AB donor. Correlation coefficients of these variables for the locally procured kidneys with the DISCARD variable show weak to moderate positive correlations except for the race variable which indicates a weak and insignificant negative correlation. Illness, child donor weight, and AB blood type hold the strongest relationships with the decision to discard kidneys.

To measure the characteristics of the nephrectomy phase of the procurement, all variables except enbloc procurement are negatively associated with a discard decision for locally procured and kept kidneys. These correlations would indicate that where transplant surgeons do not perform the nephrectomy, an enbloc procurement occurs, kidneys are not flushed insitu, kidneys are not preserved in slush, it is not a multiorgan procurement, and a shorter than average time interval between admission to the hospital and clamp time (or the time when the kidney is excised) will be associated with a discarded kidney.

Organizational characteristics of OPOs were used in the model based on aggregated numbers from the kidney disposition forms from each agency. While only percent kidneys exported from the OPO shows a meaningful, and positive, correlation with the discard decisions, the other variables were chosen to control for OPO differences in size and sophistication.

The size of the OPO, indicated by the number of cases it procured in 12 months, the risks it took shown by the percent of pediatric kidneys it pursued, the ability to pre-type donors (percent of pretyped kidneys), the level of involvement in multiorgan procurements, and the degree of sharing activity all were chosen as indicators of the OPO's level and type of procurement efforts.

Table 7:1 displays these variables for the primary analysis of discard outcomes for locally procured kidneys.

Table 7:1

Means, standard deviations, variance, Pearson Correlation Coefficients with dependent variable DISCARD, and number of cases of kidneys locally procured and kept, analyzed in stepwise multiple regression (mean substituted for missing data)

Variable	Label	Mean	Standard Deviation	Variance	Pearson Corr. Coeff.	Cases
DISCARD	Discard or transp	.058	.233	.054	---	2530
Donor characteristics						
AGE	Age of donor, yrs	29.407	14.633	214.113	.072	2513
UND40LB	Donor less than 40lb	.025	.146	.021	.095	2193
WHITE	White donor	.803	.398	.158	-.052	2530
ILLNESS	Cause of death illness	.197	.398	.158	.112	2530
ABTYPE	Blood type rare AB	.018	.134	.018	.093	2530
Nephrectomy procedure						
TPSURG	Transplant surg did neph	.805	.396	.157	-.100	2530
ENBLOC	Removed kidneys enbloc	.851	.343	.118	.061	2356
INSITU	Perfused kidneys insitu	.930	.245	.060	-.128	2342
SLUSH	Preserved kidneys- slush	.806	.396	.157	-.157	2530
MULTIORG	Multiorgan procurement	.625	.484	.234	-.130	2530
ADMXCLMP	Admit to clamp hrs	76.716	47.977	2301.773	-.055	2275
Organizational characteristics						
PCTPTYPE	OPO % pretyped kidneys	44.408	30.699	942.425	-.034	2530
PCTPEDS	OPO % ped'tric kidneys	11.178	3.155	9.952	.002	2405
NOFCASES	OPO size, # cases	254.201	160.557	25778.415	-.032	2530
PCTIMPRT	OPO % imported kidneys	13.658	9.633	92.791	-.001	2530
PCTEXPRT	OPO % exported kidneys	13.759	12.061	145.471	.132	2530
PCTMULTI	OPO % multiorgan proc.	59.510	16.459	270.893	-.005	2530

All 17 independent variables were regressed on the dependent DISCARD variable for locally procured and kept kidneys. In addition, variables indicating if an organ was imported or exported were entered for regressions on DISCARD for the subsamples of kidneys from pediatric, marginal and minority donors.

Regression results for locally procured and kept kidneys

Of the 5 variables entered measuring donor characteristics, both AGE and WHITE proved to make no statistically significant contribution to the explanation of discard decisions. However, kidneys from low weight child donors, donors with the rare AB blood type, and donors who died from illness rather than trauma were notably more likely to result in a discard decision.

In the analysis of the outcomes for local kidneys that are not shared, all six variables describing the nephrectomy process contribute to the explanation for discard decisions. Kidneys that are not preserved in slush, usually meaning that they are perfused, have the strongest association with discard decisions of all the variables in the model. Kidneys that are not excised along with other vital organs are also more likely candidates for discard decisions. Kidneys that are procured enbloc, the most common method used in pediatric procurements, are liable to be discarded even controlling for variation due to age or low donor weight.

In addition, if a transplant surgeon did not perform the nephrectomy, there is an increased chance the kidneys procured will be discarded. The negative association between admission to clamp time and discard outcome may reflect the fact that most discards occur in less than 10 hours, as discussed earlier. Unstable donors who are rushed through the procurement procedure may end up with unusable organs.

From the variables describing the organizational characteristics of the OPO, 4 of the 6 entered are meaningful. Greater sharing activity, percent of kidneys exported and imported, is associated with more frequent discard decisions as are agency size. A lower percent of pediatric cases is also related to discard outcome.

Table 7:2

Regressions for kidney discards by local disposition and from pediatric, marginal and minority donors, by selected variables

Independent Variables	Partial Correlation Coefficients: Model of discard decisions for Local Kidneys (N=2530)	Pediatric Kidneys (N=387)	Marginal Kidneys (N=333)	Minority Kidneys (N=649)
Donor characteristics				
AGE		-.298***		
UND40LB	.104***			.233***
WHITE				
ILLNESS	.086***	.196***		.158**
ABTYPE	.090***	.197***		.215***
Nephrectomy procedure				
TPSURG	-.039*			-.079*
ENBLOC	.088***		.190**	
INSITU	-.043*			
SLUSH	-.176***		-.362***	-.132**
MULTIORG	-.118***			
ADMXCLMP	-.050*			
Organizational characteristics				
PCTPTYPE		-.124*		
PCTPEDS	-.041*			
NOFCASES	.081**		.126*	
PCTIMPRT	.072**	.161**		
PCTEXPRT	.114***		.334***	.103**
PCTMULTI			-.166**	
IMPORT		-.179***		-.120**
EXPORT			-.169**	-.177***
Adjusted R-square	.102***	.151***	.315***	.168***

Significance levels are as follows:
* <= .050
** <= .010
*** <= .001

Regression results for outcomes of pediatric kidneys

The reasons for discard of pediatric kidneys vary considerably than for those of locally procured and kept kidneys. Among the donor characteristic variables, illness and AB blood type remain contributors to the decision to discard kidneys. However, it does not appear that low donor weight of less than 40 pounds affects the decision. This result may be due to the artificial limits on the variation of donor weight in this physically smaller population. The strongest predictor of discard of pediatric kidneys is donor age - the younger the donor, the more likely the chances for discard.

No nephrectomy procedure variables impact discard decisions for pediatric donor kidneys. The variables entered here to account for differences in clinical procedure have no effect on the explanation for pediatric kidney outcome.

However, OPO organizational characteristics do affect pediatric kidney discard. In agencies where kidneys are regularly imported and placed, pediatric kidneys that are locally procured and kept are more likely to result in a discard outcome.

OPOs with a higher than average likelihood of importing kidneys show themselves to be well-connected to the U.S. organ sharing system. Their local demand for organs is in part met through the import of kidneys from the larger system. It is interesting that OPOs so well-connected are more likely to discard non-imported, or local, pediatric kidneys.

The interpretation of this finding is difficult but it may be due to two causes. First, high demand for pediatric organs in these OPOs may put pressure on them to resist exporting pediatric kidneys. They may try to place kidneys locally that might be more useable elsewhere because local surgeons have identified needy and waiting recipients at home. Second, because pediatric procurement is technically more difficult there is a higher likelihood of surgically damaged kidneys. Site visit interview respondents emphasized that surgeons are willing to try to repair locally procured kidneys but resist exporting any 'mistakes.' It may be that surgeons in other areas are not willing to accept others 'mistakes,' especially for pediatric recipients. Another outcome may be that such kidneys are not offered to other teams for possible repair.

Another possible reason for the higher proportion of pediatric discards may be due to a decreasing demand for pediatric kidneys. Although the organ disposition data analyzed in these regressions do not address the issue of system-wide demand for pediatric kidneys, site visit information indicates that there is lower demand for kidneys from very small donors. Some of the discarded organs reflected here may have been retrieved as a result of a heart or liver donation with little expectation of a suitable recipient. In fact, several site visit respondents hypothesized that some transplant teams might try to underwrite another vital organ procurement through reimbursement for a failed kidney acquisition procedure.

Regression results for outcomes of marginal kidneys

Interestingly, discard of marginal kidneys is not predicted by the donor characteristics measured in this model. Neither age, donor weight, cause of death, nor blood type predicts discard.

Instead, the strongest predictors of discard come from the nephrectomy and organizational characteristics of marginal kidneys. Kidneys that must be perfused, not preserved in slush, are most likely marginal kidneys that will result in discard. Marginal kidneys from OPOs with a high percent of exports but where such kidneys are not exported also are likely to have discard outcomes.

Regression results for outcomes of minority kidneys

Where discard outcomes do result for minority kidneys, the causes are spread among donor characteristics, organizational characteristics, and lastly the nephrectomy procedure. The strongest predictors of discards are child donor weight, AB blood type, and where the kidney is not exported. It may be more difficult to place a minority kidney.

The regression analyses substantiate the hypotheses that the characteristics of donors, the nephrectomy procedure, and the OPO influence procurement outcomes. Young donor age and low donor weight, illness as cause of death, and having an AB blood type contribute to discard decisions for all four samples analyzed.

The nephrectomy procedure characteristics seem to have the strongest impact on the analysis of local kidneys with enbloc procurement and the use of perfusions both predictors of discard decisions for all groups.

The last group of variables, the organizational characteristics show some surprising differences. For local kidneys, OPO qualities such as size and fewer pediatric procurements predict discards. But it is the organ sharing attributes that are the most prevalent predictors of discards among the pediatric, marginal and minority populations. It is for these groups that a national system may have the most effect on reducing organ wastage.

Chapter 8

QUALITATIVE VALIDATION OF SURVEY FINDINGS THROUGH OPO SITE VISITS

Analysis of the quantitative data present a comprehensive overview of the factors associated with kidney discard. It is clear that discards are more likely to occur when donors are young children, among single organ donors, among people who have died because of an illness rather than a traumatic injury, where the nephrectomy has been performed by a non-transplant surgeon, using non-slush preservation, and in larger agencies where sharing, either importing or exporting organs, is common.

The quantitative data represent a large and representative sample of all kidneys procured and transplanted or discarded in 1988. However, site visits were carried out in 5 OPOs to come to a more comprehensive understanding of the causes of discarded kidneys. Intensive interviews were conducted with procurement professionals about actual cases where discards occurred.

Selection for site visit

Agencies were selected for site visit to represent four key criteria:

- o low discard rates,
- o diverse donor pools,
- o differing nephrectomy practices,
- o and a range of organizational characteristics.

Two agencies were selected with higher than average discard rates because of their reputations as being aggressive, experienced and successful in procuring donors. While average discard rates were 5.2 percent, the overall discard rate for all 5 sites visited was 4.6. Of the two with higher than average discard rates, one, a small agency located in a rural area, reported discards of 6.3 percent. The second OPO is a large, urban site, with a discard rate of 8.1 percent. However, while the other 4 OPOs defined discards as kidneys not transplanted after the organ has been removed, this agency defined a discard as any kidney not transplanted after the initial incision is made. Recalculating the discard rate according to the more prevalent definition, the discard rate would be 5.5 percent for this OPO.

Table 8:1

Number and percent of kidney procurement outcomes by all OPOs visited and not visited and by sites visited

Characteristics	All Sites			Sites Visited				
	ALL SITES	SITES NOT VISITED	SITES VISITED	SITE 1	SITE 2	SITE 3	SITE 4	SITE 5
Number of kidneys	3503	2532	971	229	272	64	293	113
Number of discards	181	136	45	11	22	4	4	4
PERCENTAGES								
Outcome rates[a,b]								
Discard Rate	5.2	5.3	4.6	4.8	8.1	6.3	1.4	3.5
Transplant Rate	93.1	92.3	95.2	94.8	91.9	93.8	98.6	95.6
Unknown outcome	1.7	2.3	0.2	0.4	--	--	--	0.8
Total	100.0	100.0	100.0	100.01	100.0	100.0	100.0	100.0

[a]Differences between sites visited and not visited, Chi square p value less than .05.
[b]Differences among sites visited, Chi square p value less than .05.

A site visit was requested at each site and approved by the OPO. Visits were scheduled and conducted from December of 1988 through June of 1989. A brief interview agenda was prepared. Questions were asked about the following areas:

- operational characteristics such as laboratory affiliation, staffing patterns, number of satellite offices, geographic factors, and relations with transplant teams;
- reasons for agency discards in 1988;
- specific procurement and/or nephrectomy characteristics that may lead to discards, including donor pre-typing, preservation methods, surgical teams;
- internal and external relationships for organ sharing, importing and/or exporting;
- relations with UNOS, particularly compliance of their agency sharing policies and procedures with UNOS requirements.

The agenda was modified according to the particular characteristics of the site, with additional questions asked where appropriate.

In preparation for each visit, computerized output of each agency's data was produced and thoroughly examined in comparison to the national data. Telephone interview data were also reviewed, and kidney distribution forms for organs discarded by the agency were assembled. After studying these data, the interview agenda was modified to focus questioning about the particular OPO's situation.

Visits lasted from 4 to 6 hours. At each visit, an intensive interview, based on the interview agenda, was conducted with the OPO representative, either the executive director or administrator. In some cases, particularly among the smaller agencies, organ procurement coordinators joined the discussion. In the process of the interview, each discard form was discussed regarding the circumstances and the outcome of the specific procurement that led to a discard. The computer print-out was also reviewed, and OPO staff were asked to compare their results with a preliminary list of national findings. Finally, any questions from agency personnel were answered. The computer print-out was given to the agency at the end of the interview.

Findings

Operational characteristics

Of the five OPOs visited, three were large, each procuring between 200 and 300 kidneys. One was medium and one was small. All were from large, densely populated urban areas except for the small OPO. This agency is located in a rural state with a geographically dispersed population and long distances between its largest city and outlying areas. The OPOs are located across the country: two in the southwest, two in the midwest, and one in the northeast.

All but one, the small OPO, have satellite locations with the central office providing organizational and administrative support. Procurement coordinators are on similar rotating call systems, regularly rotating length of call and intensity of tasks. Two are independent free-standing organizations with their own laboratory facilities, and the others are affiliated with hospitals or associated OPO groups. They all import and export organs regularly, some much more frequently than others. All were willing and able to comply with reporting requirements for the National Kidney Distribution study.

Agency views of discards

Among the sites visited, there was a wide range of attitudes regarding discards. Some OPOs felt discards should be minimized: marginal donors should not be procured, pediatric donors should only be accepted if a local transplant program reported an eligible recipient, kidneys lost before the nephrectomy (donor arrest, visibly damaged insitu) should neither be counted as procured nor discarded. Others mentioned the growing demand for organs, the aging of the recipient population, and the need for

reimbursement for operating room costs for cases that 'go bad.' In some cases, discards were attributed to the depredations of visiting transplant teams come to harvest other vital organs. All OPOs agreed that discards due to surgical errors could be minimized with better training and supervision of local surgeons. However, all recognize that the restricted time frame available for retrieving organs combined with large geographic distances and unstable donors will probably continue to result in some unusable organs.

Reasons for discards

These five sites were visited because they represent a measure of success in the organ procurement system. Most have lower than average discard rates, but even those with very low rates report having to discard some organs. An investigation of the causes for organ wastage among these agencies reveals that high procurement rates may be accompanied by some wastage. However, a comparison of the records of these sites with other sites not chosen for visit reveals some interesting differences.

Discards can occur as a consequence of donor characteristics, nephrectomy, or placement. Discards initiating in the donor stage have to do with problems with the donor that do not become apparent until the nephrectomy. Discards attributable to the nephrectomy stage are most often due to surgical complications, either technical errors or sacrificing one organ to retrieve another. The placement stage used to account for the highest loss of organs, when suitable recipient matches could not be found for viable organs. Our study shows this is changing.

Table 8:2

Numbers of kidneys discarded by OPO
reasons for discards

Characteristics	All Sites			Sites Visited				
	ALL SITES	SITES NOT VISITED	SITES VISITED	SITE 1	SITE 2	SITE 3	SITE 4	SITE 5
Number of kidneys	3503	2532	971	229	272	64	293	113
Reasons for discards (n)								
Organ pathology	52	44	8	4	2	--	--	2
Anatomically abnormal	30	17	13	2	7	2	1	1
Positive cultures*	21	20	1	--	1	--	--	--
Surgical complications	20	10	10	--	7	2	--	1
Prior organ injury	16	10	6	2	3	--	1	--
Preservation problem	15	0	--	--	--	--	--	--
Too small	12	11	1	1	--	--	--	--
Other	15	9	6	2	2	--	2	--

*Includes 2 kidneys positive for HIV.

The three most common causes of discard occur in the procurement stage: organ pathology, anatomical abnormalities, and positive (infected) donor cultures. Yet OPOs visited were much less likely to report organ pathology or positive cultures are reason for discard, indicating that perhaps these factors can be spotted before a nephrectomy begins. One OPO reported they do not begin a nephrectomy until the serology has been reported. Several others mentioned that skilled surgeons can sometimes repair anatomical abnormalities, rendering the organ usable.

Organ wastage in the nephrectomy stage may result from technical mistakes due to errors of judgement, lack of training, or competing demands for other organs from the donor. Half of all kidneys discarded due to surgical complications (10/20) can be attributed to the 5 OPOs visited, and half of these (5/10) are attributable to damage to the kidneys by a surgeon removing another organ, usually the liver. An OPO representative suggested that the costs of liver transplantation are sometimes underwritten through reimbursement for a kidney acquisition, even a failed one. Aggressive donor procurement is likely to result in more organs retrieved, but some may be damaged in the process. Some agencies think this is an acceptable price to pay to increase the supply of transplantable organs.

Wastage in the placement stage is notably missing among the OPOs visited. Although over 8 percent of all kidneys wasted were due to preservation errors,

none of the sites visited reported any problems maintaining kidneys until a recipient was available. In general, donor size was also not a problem for these agencies.

Donor, procurement, nephrectomy or organizational characteristics

The donor pools of sites visited appear to be representative of the rest of the nation. Although the sites visited differed among themselves regarding donor characteristics, they did not differ significantly from sites not visited. Their donors were similar regarding gender, race, and cause of death.

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